

Notice of Allowability	Applicant No.	Applicant(s)
	09/509,595	PELTONEN ET AL.
	Examiner	Art Unit
	Samuel W Liu	1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. This communication is responsive to 1-3-05.

2. The allowed claim(s) is/are 29, 32-34, 36-38, 42-43, 45-48, 62, 66 and 68.

3. The drawings filed on 28 March 2000 are accepted by the Examiner.

4. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of the:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. CORRECTED DRAWINGS (as "replacement sheets") must be submitted.

(a) including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
1) hereto or 2) to Paper No./Mail Date _____.

(b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of
Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- 1. Notice of References Cited (PTO-892)
- 2. Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3. Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 1-5-00
- 4. Examiner's Comment Regarding Requirement for Deposit
of Biological Material
- 5. Notice of Informal Patent Application (PTO-152)
- 6. Interview Summary (PTO-413),
Paper No./Mail Date 1-18-05.
- 7. Examiner's Amendment/Comment
- 8. Examiner's Statement of Reasons for Allowance
- 9. Other _____.

DETAILED ACTION

This Office action is in response to applicants' amendment filed 3 January 2005, which cancels claim 41, and amends claims 42 and 45. The stated amendment has been entered. Also, the applicants' request (3 January 2005) for extension of time of three months has been entered. Note that claims 1-28, 39-40 and 54 are canceled by the applicants' amendments filed 8 March 2000 and filed 22 September 2003, that claims 31, 35, 44, 63-65 and 67 are canceled by the applicants' amendment filed 7 June 2004. Thus, the pending claims 29-30, 32-34, 36-38, 42-43, 45-53, 55-62, 66 and 68 are therefore examined in this Office action.

EXAMINER'S AMENDMENT

An Examiner's Amendment to the record appears below. Should the change and/or additions be unacceptable to Applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it MUST be submitted no latter than payment of the Issue Fee.

Authorization for this examiner's amendment was given in telephone interviews with 18 January 2005. Applicants agree to cancel claims 30, 49-53 and 55-61 without prejudice and agree to amend claims 37-38, 46-48, 62 and 68.

Amendments to claims:

Delete claim 30.

Claim 37 (*Amendment*): After "1309 or 1313 of the", change "nucleotide sequence" to "nucleic acid sequence".

Claim 38 (*Amendment*): After "wherein the substitution is:", change "a cytosine to thymidine exchange at nucleotide position 889, a guanosine to thymidine exchange at nucleotide position 358, an adenine to guanosine exchange at nucleotide position 374, a guanosine to adenine exchange at nucleotide position 1052, or a cytosine to adenine exchange at nucleotide position" to "changes of cytosine to thymidine at nucleotide position 889, guanosine to thymidine at nucleotide position 358, adenine to guanosine at nucleotide position 374, guanosine to adenine at nucleotide position 1052, or cytosine to adenine at nucleotide position 1094".

Claim 46 (*Amendment*): After “an isolated”, change “host” to “host cell”.

Claim 47 (*Amendment*): Before “a plant cell”, add “or”; and after “a plant cell”, delete “a transgenic animal or a transgenic plant”.

Claim 48 (*Amendment*): After “an isolated”, change “host transformation” to “host cell transformation”; and, after “said polypeptide”, delete “from said culture or said host”.

Delete claims 49-53 and 56-61.

Claim 62 (*Amendment*): After “nucleic acid molecule”, change “has” to “comprises”.

Claim 68 (*Amendment*): After “thereof”, add “ that encodes the polypeptide of SEQ ID NO:2”.

Amendments to the specification:

Insert the following paragraph before “the “Description” paragraph:

This patent application claims foreign priority benefits. Specifically, this patent application claims the benefit of the filing date under 35 U.S.C. 120 of International Application No. PCT/EP98/06294, filed 28 March 1998, and the benefit of the filing date under 35 U.S.C. 119 of Germany Application Nos. 97117154.1, filed 2 October 1997.

In abstract is amended as follows (in one paragraph):

APECED (Autoimmune polyendocrinopathy candidiasis ectodermal dystrophy) is the only described systemic autoimmune disease with monogenic background. We have isolated a novel polynucleotide in chromosome 21q22.3 and identified five different mutations APECED patients originating from different populations. We named polypeptide, which is encoded by the said polynucleotide, APGD1 (i.e., autoimmune polyglandular disease type 1). The APGD1 polypeptide consists of 545 amino acid residues comprising two Cys(4)-His-Cys(3) double-paired finger motif similar to the PHD finger domains (zinc finger-like motifs). The identification of the polynucleotide facilitates direct genetic diagnosis of APECED and provides tools for dissection of the molecular pathogenesis of the disease.

Conclusion: Claims 29, 32-34, 36-38, 42-43, 45-48, 62, 66 and 68 are allowable over the art of record.

The following is an **Examiner's Statement of Reasons for Allowance**: Example 3 of the specification (see page 26) has described the claimed polynucleotide which has substantial and specific utility, i.e., usefulness of the polynucleotide in detecting or diagnosing Finnish patients of a disease state (i.e., autoimmune polyglandular disease type I). Thus, claims are considered allowable as indicated above.

Any comments considered necessary by applicants must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is (571) 272-0949. The Examiner can normally be reached daily except alternate Fridays from 8:30 A.M. to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Jon Weber, can be reached at (571) 272-0925. The official fax number for Technology Center 1600 is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

SWL
Samuel W. Liu, Ph.D.
Art Unit 1653, Examiner
January 18, 2005

Karen Cochrane Carlson, Ph.D.
KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER

Abstract

APECED (Autoimmune polyendocrinopathy candidiasis ectodermal dystrophy) is the only described systemic autoimmune disease with monogenic background. We have isolated a novel polynucleotide in chromosome 21q22.3 and identified five different mutations in APECED patients originating from different populations. We named polypeptide, which is encoded by the said polynucleotide, APGD1 (i.e., autoimmune polyglandular disease type 1). The APGD1 polypeptide consists of 545 amino acid residues comprising two Cys(4)-His-Cys(3) double-paired finger motif similar to the PHD finger domains (zinc finger-like motifs). The identification of the polynucleotide facilitates direct genetic diagnosis of APECED and provides tools for dissection of the molecular pathogenesis of the disease.